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Special Section: Case Law Updates

The Effect of Recent U. S. Supreme Court Decisions on State Law Claims Brought Against Pharmaceutical and Medical Device Manufacturers

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Medical Devices-FDA Premarket Approval Trumps State Law Claims

In an opinion written by Justice Antonin Scalia, the Supreme Court held in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), that the pre-emption clause enacted in the Medical Device Amendments of 1976 (the "MDA") bars state law claims challenging the safety and effectiveness of medical devices subject to the FDA's premarket approval. Premarket approval is a required process of scientific review, established by the MDA, to ensure the safety and effectiveness of Class III devices. These devices are ones that support or sustain human life or are of substantial importance in preventing impairment of human health, or that present a potential, unreasonable risk of illness or injury.

In *Riegel*, an Evergreen Balloon Catheter, a Class III device that received premarket approval from the FDA, ruptured causing injury to a coronary angioplasty patient. The doctor using the device inflated it to ten atmospheres despite the device's label warning that the catheter should never exceed eight atmospheres. Regardless, the injured patient brought suit against the device manufacturer claiming the device's design, manufacture, and label were all in violation of state law. The issue before the Court was whether these state law claims conflicted with the MDA, which contains a pre-emption clause that reads as follows:

"Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement- (1) which is **different from, or in addition to, any requirement applicable under this chapter to the device . . .**"

The Court, citing its earlier decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 512 (1996), held that state law claims regarding the safety or effectiveness of the Class III medical device constitute "additional requirements" and are in direct conflict with the MDA. Thus, per the Constitution's Supremacy Clause, federal law superseded the state law claims. The Court acknowledged that the injured patient could have brought a claim that the device violated federal law, but that no such claim was brought in this particular case.

Pharmaceuticals - Inconsistent Liability for Allegedly Inadequate Drug Labeling After *Pliva, Inc. v. Mensing*

The Supreme Court's recent decision in *Pliva, Inc. v. Mensing*, No. 09-993 (U.S. June 23, 2011), has reduced the factors used in determining whether there can be state law liability for alleged inadequate drug labeling to a simple question: Was the drug brand-name or generic? In the wake of the recent *Pliva* decision, brand-name pharmaceutical manufacturers that fail to satisfy

state law labeling requirements can be held liable to injured consumers, whereas generic drug manufacturers cannot. The distinction revolves around whether it's possible for the manufacturer to comply with both federal and state drug labeling laws. To the extent compliance with both is deemed to be impossible, as was the case for the generic drug manufacturer in *Pliva, Inc.*, state law is pre-empted and such claims will not stand.

Previously, in *Wyeth v. Levine*, 555 U.S. 555 (2009), the Supreme Court held that since it was possible for a brand-name drug manufacturer to comply with *both* state and federal drug labeling laws, state law was not pre-empted, and the manufacturer was held liable under state law for the inadequate label. In *Wyeth*, a consumer of a brand-name pharmaceutical sued the manufacturer under state law for failing to warn of the risks associated with administering the drug. The manufacturer claimed it would have needed FDA approval to provide such a warning, and the FDA's recent approval of the drug's label should preclude any state law claim that the label was insufficient. The Court held that an FDA regulation, the "changes being effected" process, CFR § 314.70(c)(6)(iii), allowed the brand-name manufacturer to strengthen its label without prior FDA approval, and since it was therefore possible for the brand-name manufacturer to satisfy both state and federal law, pre-emption was not established, and the manufacturer was held liable under the state law.

In *Pliva, Inc.*, on the other hand, the Court stated "[i]t is beyond dispute that the federal statutes and regulations that apply to brand-name drug manufacturers are meaningfully different than those that apply to generic drug manufacturers." The Court acknowledged that since federal law mandates generic drugs maintain the same label as their brand-name counterparts, it was impossible for the generic manufacturer to comply with any state law duty to update its label without violating its federal law duty to keep the label the same. Simply put, the generic manufacturer was not entitled to update its label by exercising the "changes being effected" process (mentioned above) available to brand-name manufacturers. Without the liberty to independently update its label, the generic manufacturer was caught in a classic Catch 22: fail to update the label and violate state law, or deviate from the brand-name's label and violate federal law. Thus, the Court held the federal law pre-empted the common-law duty and the state law claims were held to be invalid.

In sum, brand-name drug manufacturers can-while generic drug manufacturers cannot-be held liable under state tort law for failing to provide adequate warning labels.